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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,112	12/29/2003	Sanjay D. Khare	06843.0052-00000	1751

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,112	KHARE, SANJAY D.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-31,47-62,77-86,104-134 and 153-159* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-31,47-62,77-86,104-134 and 153-159* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 16-17, 25-31, 47, 48, 50, 56-62, are drawn to a method of treating rheumatoid arthritis by administering sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 2. Claims 16-17, 21, 25-31, 47-48, 52, 56-62, are drawn to a method of treating rheumatoid arthritis by administering sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 3. Claims 16-20, 24-31, 47, 49, 51, 55, 56-62, are drawn to a method of treating rheumatoid arthritis by administering PEG sTNFR-I, classified in Class 514, subclass 2.

Group 4. Claims 16, 22, 25-31, 47, 53, 56-62, are drawn to a method of treating rheumatoid arthritis by administering at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 5. Claims 16, 23, 25-31, 47, 54, 56-62, are drawn to a method of treating rheumatoid arthritis by administering a polypeptide as set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 6. Claims 16-17, 25-31, 47, 48, 50, 56-62, are drawn to a method of treating psoriatic arthritis by administering sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 7. Claims 16-17, 21, 25-31, 47-48, 52, 56-62, are drawn to a method of treating psoriatic arthritis by administering sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 8. Claims 16-20, 24-31, 47, 49, 51, 55, 56-62, are drawn to a method of treating psoriatic arthritis by administering PEG sTNFR-I, classified in Class 514, subclass 2.

Group 9. Claims 16, 22, 25-31, 47, 53, 56-62, are drawn to a method of treating psoriatic arthritis by administering at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 10. Claims 16, 23, 25-31, 47, 54, 56-62, are drawn to a method of treating psoriatic arthritis by administering a polypeptide as set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 11. Claims 16-17, 25-31, 47, 48, 50, 56-62, are drawn to a method of treating systemic lupus erythematosus by administering sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 12. Claims 16-17, 21, 25-31, 47-48, 52, 56-62, are drawn to a method of treating systemic lupus erythematosus by administering sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 13. Claims 16-20, 24-31, 47, 49, 51, 55, 56-62, are drawn to a method of treating systemic lupus erythematosus by administering PEG sTNFR-I, classified in Class 514, subclass 2.

Group 14. Claims 16, 22, 25-31, 47, 53, 56-62, are drawn to a method of treating systemic lupus erythematosus by administering at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 15. Claims 16, 23, 25-31, 47, 54, 56-62, are drawn to a method of treating systemic lupus erythematosus by administering a polypeptide as set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 16. Claims 16-17, 25-31, 47, 48, 50, 56-62, are drawn to a method of treating graft rejection by administering sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 17. Claims 16-17, 21, 25-31, 47-48, 52, 56-62, are drawn to a method of treating graft rejection by administering sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 18. Claims 16-20, 24-31, 47, 49, 51, 55, 56-62, are drawn to a method of treating graft rejection by administering PEG sTNFR-I, classified in Class 514, subclass 2.

Group 19. Claims 16, 22, 25-31, 47, 53, 56-62, are drawn to a method of treating graft rejection by administering at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 20. Claims 16, 23, 25-31, 47, 54, 56-62, are drawn to a method of treating graft rejection by administering a polypeptide as set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 21. Claims 16-17, 25-31, 47, 48, 50, 56-62, are drawn to a method of treating psoriasis by administering sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 22. Claims 16-17, 21, 25-31, 47-48, 52, 56-62, are drawn to a method of treating graft rejection by administering sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 23. Claims 16-20, 24-31, 47, 49, 51, 55, 56-62, are drawn to a method of treating psoriasis by administering PEG sTNFR-I, classified in Class 514, subclass 2.

Group 24. Claims 16-17, 22, 25-31, 47, 53, 56-62, are drawn to a method of treating psoriasis by administering at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 25. Claims 16, 23, 25-31, 47, 54, 56-62, are drawn to a method of treating psoriasis by administering a polypeptide as set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 26. Claims 16-17, 25-31, 47, 48, 50, 56-62, are drawn to a method of treating inflammatory bowel disease by administering sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 27. Claims 16-17, 21, 25-31, 47-48, 52, 56-62, are drawn to a method of treating inflammatory bowel disease by administering sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 28. Claims 16-20, 24-31, 47, 49, 51, 55, 56-62, are drawn to a method of treating inflammatory bowel disease by administering PEG sTNFR-I, classified in Class 514, subclass 2.

Group 29. Claims 16, 22, 25-31, 47, 53, 56-62, are drawn to a method of treating inflammatory bowel disease by administering at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 30. Claims 16, 23, 25-31, 47, 54, 56-62, are drawn to a method of treating inflammatory bowel disease by administering a polypeptide as set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 31. Claims 77-78, 80, 84-86, are drawn to a method of treating rheumatoid arthritis by administering by administering an IL-1 inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 32. Claims 77-78, 82, 84-86, are drawn to a method of treating rheumatoid arthritis by administering an IL-1 inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 33. Claims 77-78, 79, 81, 84-86, are drawn to a method of treating rheumatoid arthritis by administering an IL-1 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 34. Claims 77, 83, 84-86, are drawn to a method of treating rheumatoid arthritis by administering an IL-1 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 35. Claims 77-78, 80, 84-86, are drawn to a method of treating psoriatic arthritis by administering by administering an IL-1 inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 36. Claims 77-78, 82, 84-86, are drawn to a method of treating psoriatic arthritis by administering an IL-1 inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 37. Claims 77-78, 79, 81, 84-86, are drawn to a method of treating psoriatic arthritis by administering an IL-1 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 38. Claims 77, 83, 84-86, are drawn to a method of treating psoriatic arthritis by administering an IL-1 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 39. Claims 77-78, 80, 84-86, are drawn to a method of treating SLE by administering by administering an IL-1 inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 40. Claims 77-78, 82, 84-86, are drawn to a method of treating SLE by administering an IL-1 inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 41. Claims 77-78, 79, 81, 84-86, are drawn to a method of treating SLE by administering an IL-1 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 42. Claims 77, 83, 84-86, are drawn to a method of treating SLE by administering an IL-1 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 43. Claims 77-78, 80, 84-86, are drawn to a method of treating graft rejection by administering by administering an IL-1 inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 44. Claims 77-78, 82, 84-86, are drawn to a method of treating graft rejection by administering an IL-1 inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 45. Claims 77-78, 79, 81, 84-86, are drawn to a method of treating graft rejection by administering an IL-1 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 46. Claims 77, 83, 84-86, are drawn to a method of treating graft rejection by administering an IL-1 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 47. Claims 77-78, 80, 84-86, are drawn to a method of treating psoriasis by administering by administering an IL-1 inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 48. Claims 77-78, 82, 84-86, are drawn to a method of treating psoriasis by administering an IL-1 inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 49. Claims 77-78, 79, 81, 84-86, are drawn to a method of treating psoriasis by administering an IL-1 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 50. Claims 77, 83, 84-86, are drawn to a method of treating psoriasis by administering an IL-1 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 51. Claims 77-78, 80, 84-86, are drawn to a method of treating inflammatory bowel disease by administering by administering an IL-1 inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 52. Claims 77-78, 82, 84-86, are drawn to a method of treating inflammatory bowel disease by administering an IL-1 inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 53. Claims 77-78, 79, 81, 84-86, are drawn to a method of treating inflammatory bowel disease by administering an IL-1 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 54. Claims 77, 83, 84-86, are drawn to a method of treating inflammatory bowel disease by administering an IL-1 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 55. Claims 104-105, 107-108, 113-121, are drawn to a method of treating rheumatoid arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 56. Claims 104-105, 109, 113-121, are drawn to a method of treating rheumatoid arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 57. Claims 104, 106, 113-121, are drawn to a method of treating rheumatoid arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 58. Claims 104, 110, 113-121, are drawn to a method of treating rheumatoid arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 59. Claims 104, 111, 113-121, are drawn to a method of treating rheumatoid arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 60. Claims 104-105, 107-108, 113-121, are drawn to a method of treating psoriatic arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 61. Claims 104-105, 109, 113-121, are drawn to a method of treating psoriatic arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 62. Claims 104, 106, 113-121, are drawn to a method of treating psoriatic arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 63. Claims 104, 110, 113-121, are drawn to a method of treating psoriatic arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 64. Claims 104, 111, 113-121, are drawn to a method of treating psoriatic arthritis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 65. Claims 104-105, 107-108, 113-121, are drawn to a method of treating SLE by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 66. Claims 104-105, 109, 113-121, are drawn to a method of treating SLE by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 67. Claims 104, 106, 113-121, are drawn to a method of treating SLE by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 68. Claims 104, 110, 113-121, are drawn to a method of treating SLE by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 69. Claims 104, 111, 113-121, are drawn to a method of treating SLE by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 70. Claims 104-105, 107-108, 113-121, are drawn to a method of treating graft rejection by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 71. Claims 104-105, 109, 113-121, are drawn to a method of treating graft rejection by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 72. Claims 104, 106, 113-121, are drawn to a method of treating graft rejection by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 73. Claims 104, 110, 113-121, are drawn to a method of treating graft rejection by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 74. Claims 104, 111, 113-121, are drawn to a method of treating graft rejection by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 75. Claims 104-105, 107-108, 113-121, are drawn to a method of treating psoriasis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 76. Claims 104-105, 109, 113-121, are drawn to a method of treating psoriasis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 77. Claims 104, 106, 113-121, are drawn to a method of treating psoriasis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 78. Claims 104, 110, 113-121, are drawn to a method of treating psoriasis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 79. Claims 104, 111, 113-121, are drawn to a method of treating psoriasis by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 80. Claims 104-105, 107-108, 113-121, are drawn to a method of treating IBD by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 81. Claims 104-105, 109, 113-121, are drawn to a method of treating IBD by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 82. Claims 104, 106, 113-121, are drawn to a method of treating IBD by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 83. Claims 104, 110, 113-121, are drawn to a method of treating IBD by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 84. Claims 104, 111, 113-121, are drawn to a method of treating IBD by administering at least one of an AGP3 inhibitor, a BAFFR inhibitor and a TACI inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 85. Claims 122, 123, 125, 131-134, are drawn to a method of treating RA by administering an OX40 ligand inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 86. Claims 122, 123, 127, 131-134, are drawn to a method of treating RA by administering an OX40 ligand inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 87. Claims 122, 124, 126, 130, 131-134, are drawn to a method of treating RA by administering a OX40 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 88. Claims 122, 128, 131-134, are drawn to a method of treating RA by administering a OX40 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 89. Claims 122, 129, 131-134, are drawn to a method of treating RA by administering a OX40 inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 90. Claims 122, 123, 125, 131-134, are drawn to a method of treating psoriatic arthritis by administering an OX40 ligand inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 91. Claims 122, 123, 127, 131-134, are drawn to a method of treating psoriatic arthritis by administering an OX40 ligand inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 92. Claims 122, 124, 126, 130, 131-134, are drawn to a method of treating psoriatic arthritis by administering a OX40 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 93. Claims 122, 128, 131-134, are drawn to a method of treating psoriatic arthritis by administering a OX40 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 94. Claims 122, 129, 131-134, are drawn to a method of treating psoriatic arthritis by administering a OX40 inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 95. Claims 122, 123, 125, 131-134, are drawn to a method of treating SLE by administering an OX40 ligand inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 96. Claims 122, 123, 127, 131-134, are drawn to a method of treating SLE by administering an OX40 ligand inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 97. Claims 122, 124, 126, 130, 131-134, are drawn to a method of treating SLE by administering a OX40 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 98. Claims 122, 128, 131-134, are drawn to a method of treating SLE by administering a OX40 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 99. Claims 122, 129, 131-134, are drawn to a method of treating SLE by administering a OX40 inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 100. Claims 122, 123, 125, 131-134, are drawn to a method of treating graft rejection by administering an OX40 ligand inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 101. Claims 122, 123, 127, 131-134, are drawn to a method of treating graft rejection by administering an OX40 ligand inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 102. Claims 122, 124, 126, 130, 131-134, are drawn to a method of treating graft rejection by administering a OX40 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 103. Claims 122, 128, 131-134, are drawn to a method of treating graft rejection by administering a OX40 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 104. Claims 122, 129, 131-134, are drawn to a method of treating graft rejection by administering a OX40 inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 105. Claims 122, 123, 125, 131-134, are drawn to a method of treating psoriasis by administering an OX40 ligand inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 106. Claims 122, 123, 127, 131-134, are drawn to a method of treating psoriasis by administering an OX40 ligand inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 107. Claims 122, 124, 126, 130, 131-134, are drawn to a method of treating psoriasis by administering a OX40 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 108. Claims 122, 128, 131-134, are drawn to a method of treating psoriasis by administering a OX40 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 109. Claims 122, 129, 131-134, are drawn to a method of treating psoriasis by administering a OX40 inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 110. Claims 122, 123, 125, 131-134, are drawn to a method of treating IBD by administering an OX40 ligand inhibitor and sTNFR-I linked to an Fc region, classified in Class 514, subclass 2.

Group 111. Claims 122, 123, 127, 131-134, are drawn to a method of treating IBD by administering an OX40 ligand inhibitor and sTNFR-II linked to an Fc region, classified in Class 514, subclass 2.

Group 112. Claims 122, 124, 126, 130, 131-134, are drawn to a method of treating IBD by administering a OX40 inhibitor and PEG sTNFR-I, classified in Class 514, subclass 2.

Group 113. Claims 122, 128, 131-134, are drawn to a method of treating IBD by administering a OX40 inhibitor and at least one of etanercept, infleximab and D2E7, classified in Class 514, subclass 2.

Group 114. Claims 122, 129, 131-134, are drawn to a method of treating IBD by administering a OX40 inhibitor and a TNF-α protein of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 2.

Group 115. Claims 153-158, are drawn to a method of treating a TNF mediated diseases by administering a TNF-α inhibitor (PEG-sTNFRI), a B7 inhibitor and CTLA-4, classified in Class 514, subclass 2.

Group 116. Claims 153-157, 159, are drawn to a method of treating a TNF mediated diseases by administering a TNF-α inhibitor (etanercept), a B7 inhibitor and CTLA-4, classified in Class 514, subclass 2.

Should any one of the Groups from 1-46 be elected, Applicant is required to select one specific TNF-α inhibitor eg. sTNFR-II. Once one TNF-α inhibitor is selected, all the other TNF-α inhibitors will be withdrawn from consideration.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed

to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions 1-116 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. For example, invention 1 requires search and consideration of therapeutic efficacy of administering the sTNFRI polypeptide in the treatment of rheumatoid arthritis, while invention 4, for example, requires search and consideration of a method of treating rheumatoid arthritis by administering etanercept. Therefore, a search and examination of all the methods in one patent application would result in an undue burden.

Furthermore, inventions 1-116 are independent and distinct, each from the other, because the methods are practiced with materially different products, which are structurally and chemically different, the novelty of the inventions lying in the products being administered and not the processes. For example, in Groups 1-116, the only feature in common in the instant inventions is "a method of treating a TNF-α mediated disease", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as an antibody to TNF-α. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of

the literature for an association of sTNFR-II with rheumatoid arthritis would not necessarily reveal art for an association of the polypeptide of SEQ ID NO:4 with rheumatoid arthritis.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Election of Species

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

For Groups 1-30, Applicants are required to elect one of the following species of B7 and CD28 inhibitor selected from:

(i) CTLA4;

(ii) CTLA4-Fc;

(iii) an antagonist CD28 antibody; and

(iv) an antagonist B7 antibody.

Additionally, for Groups 55-84, Applicants are required to elect one of the following species of AGP3, BAFFR or TACI inhibitor selected from:

(a) TACI soluble receptor molecule;

(b) peptide inhibitor of AGP3;

(c) AGP3 peptibody; and

(d) a protein of SEQ ID NO:1.

Additionally, for Groups 115-116, Applicants are required to elect one of the following species of dosage selected from:

(a) the dosage recited in claim 153;

(b) the dosage recited in claim 154;

(c) the dosage recited in claim 155;

(d) the dosage recited in claim 156; and

(e) the dosage recited in claim 157.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 29-31, 47, 56-57, 60-62, 77, 84-86, 104, 113-114, 119-121, 122, 132-134, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
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